REMARKS

In the Office Action dated May 27, 2003, Claims 1-24 are pending, with Claims 2-3, 6-7, 9-10, 13-14, 16-18 and 20-24 withdrawn from further consideration. Claims 1, 4-5, 8, 11-12, 15 and 19 are currently under consideration on the merits. The specification has been objected to for certain drawing informalities. Claims 1, 4-5, 8, 11-12, 15 and 19 have also been objected to as allegedly drawn to non-elected embodiments. Claims 5 and 12 are rejected under 35 U.S.C. 101 as allegedly lacking utility. Claim 19 is rejected under 35 U.S.C. 112, first paragraph as allegedly lacking enabling support. Claims 1, 4-5, 8, 11-12 and 15 have been rejected under 35 U.S.C. 112 as allegedly lacking descriptive support in the specification. Claims 1, 4-5, 8, 11-12, 15 and 19 have been rejected under 35 U.S.C. 112, second paragraph as allegedly indefinite. Claims 1, 4, 8, 11 and 15 have been rejected under 35 U.S.C. 102(e) as allegedly anticipated by Bowtell, U.S. Patent No. 5,843,646 (hereinafter "Bowtell").

This Response addresses each of the Examiner's rejections. Applicants therefore respectfully submit that the present application is in condition for allowance. Favorable consideration of all pending claims is therefore respectfully requested.

Claims 1, 4-5, 8, 11-12, 15 and 19 have been objected to for certain informalities because the claims are directed to nonelected embodiments (i.e., to nucleic acid sequences other than the mcg7 gene and protein which are described by SEQ ID NOS: 4-5). In response, Applicants have amended the claims to obviate the objection and withdrawal thereof is respectfully requested.

Claims 5 and 12 have been rejected under 35 U.S.C. §101 as allegedly lacking utility. Specifically, the Examiner states that this ground of rejection is limited to those embodiments recited in the Markush groups of nucleotide sequences in these claims that are

limited to SEQ ID NOS: 4 and 5. The Examiner acknowledges that the specification identifies the nucleic acids as encoding a protein having guanine nucleotide exchange factor (GEF) activity based on homology to other known sequences. However, the Examiner alleges that proteins comprising such a GEF domain can have very different functions and the specification does not provide a basis for one skilled in the art to visualize what function the whole protein may have in an actual cell. The Examiner further alleges, based on the Berendsen reference (Science, Vol. 282, 642-43,1998), that it is unlikely that one can assign a definite specific function to MCG7 protein based upon limited homology to proteins known in the art at the time when the present application was filed. Moreover, Claims 5 and 12 have also been rejected under 35 U.S.C. §112, first paragraph. Specifically, the Examiner alleges that, because the claimed invention is not supported by either a specific and substantial asserted utility or a well-established utility, one skilled in the art would not know how to use the claimed invention.

In the first instance, Applicants respectfully submit that Claim 5, as amended, is directed to nucleotides encoding MCG7, not to all proteins having GEF activity. Applicants have cancelled Claim 12, without prejudice, in an effort to expedite favorable prosecution. Applicants submit that the function of the MCG7 protein has been disclosed throughout the specification on page 20, line 27 to page 21, line 4, for example. In this regard, the Examiner's attention is directed to the fact that the specification discloses how to use the present invention on page 21, lines 6-11, for example, without undue experimentation. Specifically, the specification discloses that MCG7 is a GEF involved in signal transduction, and a mutation of which can result in defective control of cell proliferation leading to the development or a propensity to develop various types of cancer. The present invention is directed to a method of detecting a condition caused or facilitated by an aberration in mcg7 gene. Thus, the specification

discloses specific and substantial utility of the present invention.

Moreover, Applicant respectfully submits that the Examiner has misapprehended the disclosure of Berendsen. Berendsen teaches that it is one of the most demanding challenges to predict the native conformation of a protein from a known amino acid sequence. (See page 643). The main reason is that it might take an unreasonably long time for existing computers to sample enough configurations to come up with the thermodynamically stable native protein structure. Id. Contrary to the disclosure of Berendsen, the present invention is not directed to computer-calculated protein structures based on known amino acid sequence. The function of the presently claimed molecules of the present invention is identified by homology analysis, which is the method used in the art to predict protein functions. In fact, Berendsen indicates that "[the] obvious route to (predict protein function) . . . is by homology modeling." Id. Accordingly, the rejections under 35 U.S.C. §§ 101 and 112, as allegedly lacking utility, are believed to be overcome and withdrawal thereof is respectfully requested.

Claim 19 has been rejected under 35 U.S.C. §112, first paragraph, as allegedly lacking descriptive support. Specifically, the Examiner acknowledges that the specification teaches that the coding sequence of mcg7 has been determined from cDNA sequences, and that judging from homology comparisons, the encoded protein has a GEF activity. However, the Examiner alleges that no specific activity of the entire protein is described. The Examiner alleges that the prior art teaches that there are different classes of proteins that possess GEF activity. Therefore, the Examiner concludes that there is no structural/functional basis for one of skill in the art to envision a particular disease or condition associated with an aberration in the mcg7 sequence, much less which aberration or change would be associated with the condition.

In response, Applicants have amended Claim 19 to clarify that the mcg7 has a nucleotide sequence set forth in SEQ ID NO:4. Applicants submit that Claim 19, as amended, is not directed to the complete sequence of the mcg7 cDNA sequence, but to the coding region as set forth in SEQ ID NO: 4. Therefore, one skilled in the art would reasonably expect that the inventors, at the time the application was filed, had possession of the claimed invention. Accordingly, the rejection of Claim 12 under 35 U.S.C. §112, first paragraph is overcome and withdrawal thereof is respectfully requested.

Claims 1, 4-5, 8, 11-12 and 15 have been rejected under 35 U.S.C. §112, first paragraph as allegedly lacking descriptive support. Specifically, the Examiner alleges that the claims encompass almost any number of proteins that can function in some fashion as a regulator of gene expression. The Examiner indicates that the specification provides a comparison of the nucleotide sequence and deduced amino acid sequence for human MCG7 to a couple of different sequences known in the art. However, the Examiner alleges the specification does not provide a basis for one skilled in the art to envision a sufficient number of different GEFs that are found in nature to describe the claimed genus. Based on Berendsen again, the Examiner alleges that there is no basis provided by the specification to enable the skilled artisan to envision what other proteins that satisfy the similarity requirement will look like, and still retain MCG7 activity.

In the first instance, as previously stated, the Examiner appears to have misapprehended the teachings of Berendsen by confusing prediction of protein function with homology analysis and calculating a protein structure based on amino acid sequence. However, in an effort to expedite favorable prosecution, Claims 1, 5, 8 and 15 have been amended and Claims 4 and 11-12, cancelled without prejudice. Accordingly, the specification clearly conveys to one skilled in the art that the inventors had possession of the claimed invention and

withdrawal of the rejection of Claims 1, 4-5, 8, 11-12 and 15 under 35 U.S.C. §112, first paragraph is respectfully requested.

Claims 1, 4-5, 8, 11-12, 15 and 19 have been rejected under 35 U.S.C. §112, second paragraph, as allegedly indefinite. Specifically, the Examiner alleges that Claims 1, 4, 8, 11 are vague and indefinite in that the metes and bounds of the term "a derivative" of a gene regulator (e.g. a GEF protein) are unclear. The Examiner alleges that the nature and number of steps necessary to obtain a "derivative" of a gene regulatory protein are unclear. The Examiner suggests that it would be remedial to delete this term from the claim language. Applicants respectfully submit that the specification discloses, in detail, the nature and number of steps to obtain a "derivative" of MCG7, on page 31, line 23 to page 37, line 19, for example.

The Examiner further alleges that Claim 8 is indefinite in that the metes and bounds of the phrases "a vector portion" and "a gene portion" are unclear. The Examiner suggests that it would be remedial to amend the claim language to indicate the minimum amount of nucleic acids that can qualify as a "portion" of a gene or vector in context of the claim. The Examiner also alleges that Claim 8 is indefinite in that it recites "a gene portion comprising a regulator of gene expression." The Examiner suggests that it would be remedial to amend the claim language to indicate that the gene encodes the protein. Applicants have amended Claim 8 in accordance with the Examiner's recommendation.

The Examiner alleges that Claim 15 is vague and indefinite in that the metes and bounds of the phrase "a gene regulator having the identifying characteristics of ...MCG7...having...an amino acid sequence of SEQ ID NO: 5" are unclear. The Examiner alleges that it is unclear what the "identifying characteristics" of MCG7 are. The Examiner suggests that it would be remedial to amend the claim language to indicate what is meant by the

term "identifying characteristics." In response, Claim 15 has been clarified to recite "a gene regulator having GEF activities of MCG7 having an amino acid sequence of SEQ ID NO: 5."

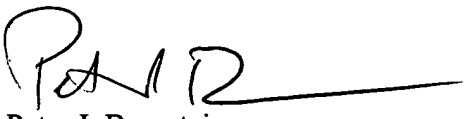
The Examiner alleges that Claim 19 is vague and indefinite in that the use of the phrases "the presence of a single or multiple nucleotide substitution, deletion and/or addition or other aberration to one or both alleles of mcg7" and "such a nucleotide substitution, deletion and/or addition or other aberration" makes it unclear as to the nature and number of combinations of different alterations of mcg7 sequence that are permissible. The Examiner further alleges that Claim 19 is indefinite by reciting the word "may." Moreover, the Examiner indicates that Claim 19 lacks a clear antecedent basis for the phrase "propensity to develop." In response, Applicants have amended Claim 19. Accordingly, the claims are clear and definite and withdrawal of the rejections under 35 U.S.C. §112, second paragraph, is respectfully requested.

Claims 1, 4, 8, 11 and 15 have been rejected under 35 U.S.C. §102(e) as allegedly anticipated by Bowtell (U.S. Patent No. 5,843,646) ("Bowtell"). Specifically, the Examiner alleges that these claims read on any nucleic acid encoding any protein. The Examiner indicates that Bowtell teaches nucleic acids and vectors comprising nucleic acids that encode the murine Son of Sevenless protein, which is a GEF involved in signal transduction pathways that activate several different genes. Applicants submit that the foregoing amendment to Claims 1, 8 and 15, and cancellation of Claims 2 and 11, render the Examiner's rejection moot and withdrawal thereof is respectfully requested.

Finally, the drawings have been objected to. Specifically, the Examiner indicates that Figures 7 and 28 are of insufficient reproducible quality (half-tone). Applicants will endeavor to obtain clearer copies of the figures and provide same in a supplemental response in due course.

In view of the foregoing Amendment and the Remarks, it is believed that the subject case is in condition for allowance, which action is earnestly solicited.

Respectfully submitted,



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